Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 24/2052950A***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***ACE Pharmaceuticals B.V.***
Site address: ***Schepenveld 41, Zeewolde, 3891 ZK, Netherlands***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000062*** / ***LOC-100005933***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***109098 F*** in accordance with Art. 40 of Directive 2001/83/EC, transposed in the following national legislation:Art. 100 of the Medicines Act.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-06-27***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

---

[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.12 Suppositories 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.12 Suppositories 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised

2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.4 Other: Sterile products in primary packaging.(en)

Clarifying remarks (for public users)

Section Quality control testing - 1.6.2 - Microbiological: non-sterility, is restricted to tests for the determination of bioburden and endotoxin content.

2026-03-31

Name and signature of the authorised person of the Competent Authority of Netherlands

---

Confidential
Health And Youth Care Inspectorate
Tel:***Confidential***
Fax:***Confidential***